



December 9, 2025



Presenters

- Robert Hood, PhD
 - Director of Accreditation and Global Development
- Jemelle Williams, BS, PMP
 - Assistant Director of Operations

Moderator

- Nichelle Cobb, PhD, CIP
 - Senior Advisor for Strategic Initiatives

Introductions and conclusions

- Lori Kravchick, BA
 - Director of Administration



What is “Ask AAHRPP”?

- Bimonthly (six times per year) webinar with:
 - Practical approach to achieving and maintaining accreditation
 - Brief presentations on topics relevant to organizations applying for initial accreditation or reaccreditation
 - An emphasis on Q&A on topics presented as well as questions submitted when participants register
 - Organized around the steps in the accreditation process
- Open and free to everyone
- Recordings available



FYIs

- Please provide feedback by completing the survey –
 - Look for the link in a follow-up email
- A link to the webinar will be sent to those who registered
 - Including links to prior “Ask AAHRPP” webinars
- If you have any questions during the session, please use the Q&A function to submit them

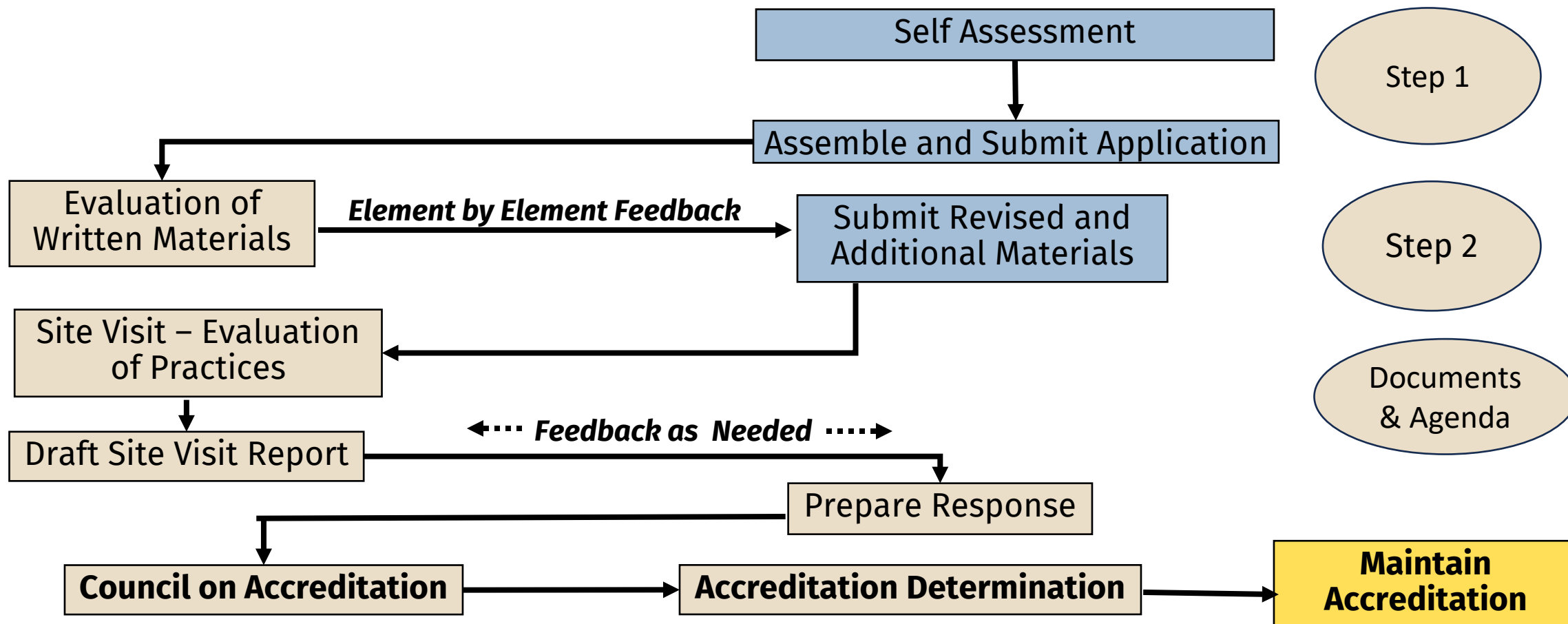


Maintaining Accreditation

<https://aahrpp.org/accreditation/maintain-accreditation/applying-for-reaccreditation>



Accreditation Process



<https://aahrpp.org/accreditation/get-accredited/overview>

Maintaining Accreditation Learning Objectives

- Respond to Council on Accreditation requests after Council
 - Status Reports and Improvement Plans – purpose is to confirm program improvements are implemented
- Understand the difference between AAHRPP's three reporting requirements:
 - Annual Reports – submit **yearly**
 - Notification of substantive program changes – submit **within 30 days**
 - Notification of other reportable events – submit as soon as possible but **within 48 hours**
- Ask AAHRPP course review – examples of the Step 1 report, Draft Site Visit Report, and Council's final report

Responding to Council Requests: Status Reports Improvement Plans

Responding to Council Requests

- Changes made by the organization to address requests after Council's review. Changes should:
 - Demonstrate the organization meets AAHRPP Standards, and
 - If education or training (or additional education or training) was planned at a prior review, then confirm it has now been completed, and
 - If monitoring or additional monitoring was planned, confirm the organization meets the Standard or Element by providing a summary of monitoring.
- Changes should be implemented prior to when the Status Report or Improvement Plan is due
- Review instructions for submitting a Status Report:
<https://www.aahrpp.org/resources/for-accreditation/additional-resource/instructions-for-preparing-a-status-report>

Monitoring to confirm the organization meets the Standard

1. What evaluation or monitoring are you conducting to show this? When there are multiple concerns under a Standard or Element, describe what was evaluated to confirm the Standard is now met.
2. Who conducted monitoring to confirm the Standard is now being met in practice and, when applicable, confirmed the organization is complying with applicable regulations?
3. When did monitoring start to confirm the Standard is now met? Confirm your organization meets the Standard prior to sending a response; otherwise, provide a specific timeline of how you will confirm the Standard is now met.
4. What additional monitoring is planned, if applicable?
5. Who reviewed results of the monitoring and assessed whether the education, training, or other actions taken were effective?
6. What changes were made, if any, as a result of the monitoring?
7. Who will review the results of future monitoring to evaluate whether additional changes, if any, are required?

Example Response:

To confirm that when the IRB/EC requests substantive changes they are returned to the convened IRB for approval, the monitoring plan described in the response to the Draft Site Visit Report has been completed. The IRB/EC manager monitored the electronic system and two sets of minutes per IRB/EC for 4 months (12 sets of minutes in total) and confirmed substantive changes are returned to the convened IRB/EC.

Documentation is provided that the IRB/EC manager and IRB/EC chair met monthly and reviewed the results of monitoring.

Examples of supporting documentation:

Document 1: Spreadsheet summarizing monitoring (page xx)

Document 2: Copies of relevant portions of minutes demonstrating minutes meet AAHRPP requirements, with relevant portions highlighted (page xx)

Document 3: Summary of meeting to review results, listing who attended (page xx)

Council may request two types of responses:

Status Reports

Purpose: Document for the Council on Accreditation activities performed to meet a Standard where there is a specific concern or to report on progress of any areas or activities in transition

Due Date: 4 months

[Instructions for Preparing a Response to Requests from the Council on Accreditation: Status Reports](#)

Improvement Plans

Purpose: Document for the Council on Accreditation corrective actions an organization has taken or will take to satisfy any unmet accreditation standards.

Due Date: 1 month

[Instructions for Preparing a Response to Requests from the Council on Accreditation: Improvement Plans](#)

Reporting

Annual Report

Due Date: **Each year**

- **March 15**
- **June 15**
- **September 15**
- **December 15**

Exceptions:

An Annual Report is **NOT DUE** the years 1) an organization submits an Application for Reaccreditation and 2) the Application for Reaccreditation is reviewed by Council

What information is included in an Annual Report?

- Organizational Changes (mergers or acquisition, entity type, etc.)
- Changes in Resources (10% or more reduction or changes)
- Changes in Program Scope (new research program, etc.)
- Addition, removal, or modification of functions, committees, or IRBs.
- Changes in method of providing services, such as use of external IRBs or contracting for services from another organization.
- Catastrophic event that results in an interruption or discontinuance in a part of or the entire Human Research Protection Program.

How to submit an Annual Report

- Reminder email will be sent to the Application Contact 60 days prior to the due date
- **The Annual Report is submitted to AAHRPP via an online survey monkey link**
- [Guidance on Completing the Annual Report Form](#)

To: reporting@aahrpp.org

From: reporting@aahrpp.org via surveymonkey.com

Subject: AAHRPP 2025 Annual Report

AAHRPP 2025 ANNUAL REPORT

Greetings from AAHRPP!

The anniversary of your organization's AAHRPP accreditation date is approaching.

To facilitate your successful completion of this Annual Report survey, we have uploaded to our website a document of the questions that you may be required to answer and guidance for completing the Annual Report. We recommend using these documents to prepare your answers before officially submitting them through this online survey.

Once you are ready to submit your responses, you may do so by clicking the button below. Once you submit your Annual Report, a link to claim your copy will be emailed automatically to you. If you have any questions, please contact reporting@aahrpp.org.

Thank you,
AAHRPP Operations

Other Reporting

Negative Government Actions

48 Hours

- OHRP Determination Letters
- FDA Warning Letters
- FDA 483 Official Action Indicated
- FDA Restrictions on IRBs or Investigators,
- Compliance actions taken by non-US authorities

Legal Issues Related to HRPP

48 Hours

- Litigation
- Arbitration
- Settlements

Negative Press Coverage Related to HRPP

48 Hours

- Radio
- TV
- Newspaper
- Online Publications

Major Organizational Change

30 days

- Name Change
- Change in Corporate Structure
- Change of Ownership or Leadership

Reporting*

Annual Reports

Organizational Changes

Issues Requiring Prompt Reporting

Questions?

Contact AAHRPP at reporting@aahrpp.org

***Source: Accreditation Procedures:**

<https://www.aahrpp.org/resources/for-accreditation/procedure/procedure-doc-1/annual-and-other-notification-reporting>

Course Review: How it all fits together

2025 sessions described the **entire process** from self-assessment to review by Council.

- **Self Assessment**
- **Step 1 Report** – the review of written materials to ensure they meet AAHRPP requirements, laws, regulations, and guidance
- **Draft Site Visit Report (DSVR)** – observations and/or areas of concern based on interviews and review of documents during the site visit
- **Response and Final Site Visit Report** – after the site visit, organizations have an opportunity to respond to the DSVR; the DSVR and the organization's response is reviewed by Council
- **Status Reports and Improvement Plans**
- **Annual Reports**

Review of two examples

- **Domain I:** Emergency preparedness and response to ensure continuity of operations to ensure protection of human participants during an emergency (Element I.1.H.)
 - **Step 1** required creation of policies;
 - **Site visit:** site visitors observed people were not knowledgeable
 - **Site visit response:** the response confirmed protections are now implemented
- **Domain III:** Researchers report conflicts of interests, and conflicts are managed (III.1.B.)
 - **Step 1** found policies were acceptable; site visitors observed researchers were not knowledgeable; the response showed improvements had started but were not complete; Council requested status report

Step 1 Report - Emergency Preparedness and Response

- Add to written materials:
 - An emergency preparedness and response plan, which addresses how continuity of operations will be maintained to ensure human participant protections during an emergency.
- Describe in written materials:
 - The process to evaluate the emergency preparedness and response plan. The description may include, for example:
 - Who is responsible for conducting the evaluation.
 - How frequently such an evaluation will occur.
 - The process for using the results, when necessary, to make adjustments to the plan to ensure continuity of operations.
 - The process to provide education about the organization's emergency response and preparedness plan for IRB/EC members and staff, researchers.

Draft Site Visit Report - Emergency Preparedness

Observations

- The organization had an emergency preparedness and response plan that addressed how continuity of operations will be maintained to ensure human participant protections during an emergency.

Areas of Concern

- HRPP staff had **not evaluated** the emergency preparedness and response plan. HRPP staff were not knowledgeable about who was responsible to annually evaluate the emergency preparedness and response plan, what was supposed to be evaluated, and how the results were to be used to make improvements if necessary.
- **Education had not occurred** annually as required in policies. HRPP staff, IRB/EC members, and researchers and research **staff were not knowledgeable** about the specific actions required by their roles required to maintain continuity of operations and protect participants in the event of an emergency. (Element I.1.H.)

Response to the Final Site Visit Report - Emergency Preparedness

Areas of Concern

HRPP staff had not evaluated the emergency preparedness and response plan. HRPP staff were not knowledgeable about who was responsible to annually evaluate the plan.

Education of members of the HRPP was planned but had not occurred. HRPP staff, IRB/EC members, and researchers and research staff were not knowledgeable about the specific actions required by their roles required to maintain continuity of operations and protect participants in the event of an emergency. (Element I.1.H.)

Response

The HRPP Director, IRB/EC chairs, and medical director **completed an evaluation** within 30 days. The response described the results of the evaluation, which identified the need to update the plan when staff changed. **Policies were clarified** to indicate the HRPP director is responsible for updating the plan. **Education had been completed** for members of the HRPP.

Council Determination

Standard is met

Step 1 Report - Researcher conflict of interest

The Step 1 review determined policies were satisfactory. Policies describe:

- the criteria and process for researchers and research staff to disclose conflicts of interest annually and to confirm disclosures upon submission of each new research study.
- the process to determine whether disclosed interest constituted a financial interest. Policies described how conflicts would be managed, and the communication of management plans to the IRB/EC.

Draft Site Visit Report - Researcher conflicts of interest

Areas of Concern

Researchers were generally **not knowledgeable about criteria requiring disclosures** of potential conflicts of interest.

Researchers and research staff were **generally not knowledgeable about requirements to complete a conflict of interest disclosure form**.

Some researchers reported their **staff complete conflict of interest disclosure forms on their behalf** when submitting IRB/EC applications.

In practice, the IRB did not review management plans, and conflicts of interest were not identified or managed.

Response to the Final Site Visit Report - Researcher conflict of interest

Response

Four hours of continuing **education was completed** within 30 days* for all researchers and research staff and IRB/EC members and staff on requirements for disclosure of conflicts of interest in research. (*Prior to the response being submitted)

Policies were reviewed, and IRB/EC staff created a worksheet to confirm conflict of interest disclosures were complete.

Researchers started to complete disclosures for all research (including approved studies), with a plan to complete all disclosures within 60 days. IRB/EC review of any studies with a conflict of interest were planned to be completed within 60 days to ensure conflicts were appropriately managed. Compliance auditors, who had not previously assessed conflict of interest disclosures, **started to include monitoring** of conflict of interest disclosures, and had completed 30 audits, and planned to audit the remainder of open studies with 90 days.

Standard is met with a status report

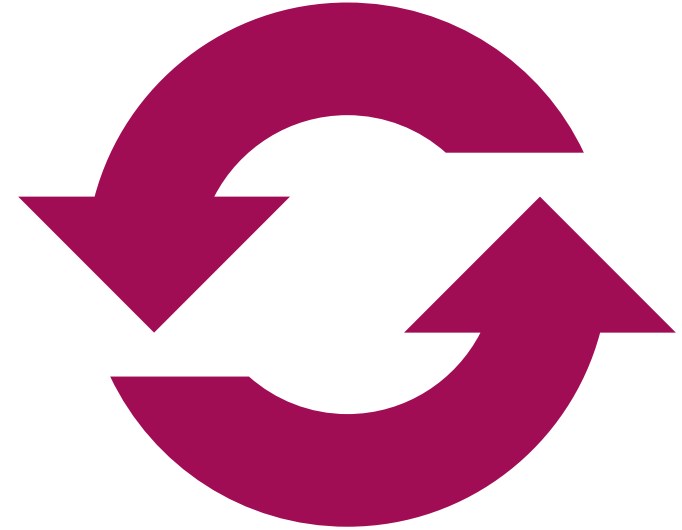
Sample Request for a Status Report: Status Report for researcher and research staff conflicts of interest

Standard is met with status report:

Confirm conflict of interest disclosure forms had been completed by all researchers.

Monitor review of conflict of interest disclosure forms and determinations that there is no financial or other conflict of interest, or that financial conflicts of interest were present. For researchers with financial conflicts of interest, confirm monitoring plans were developed. Confirm the IRB/EC reviewed all conflict of interest management plans.

Maintaining information about your organization



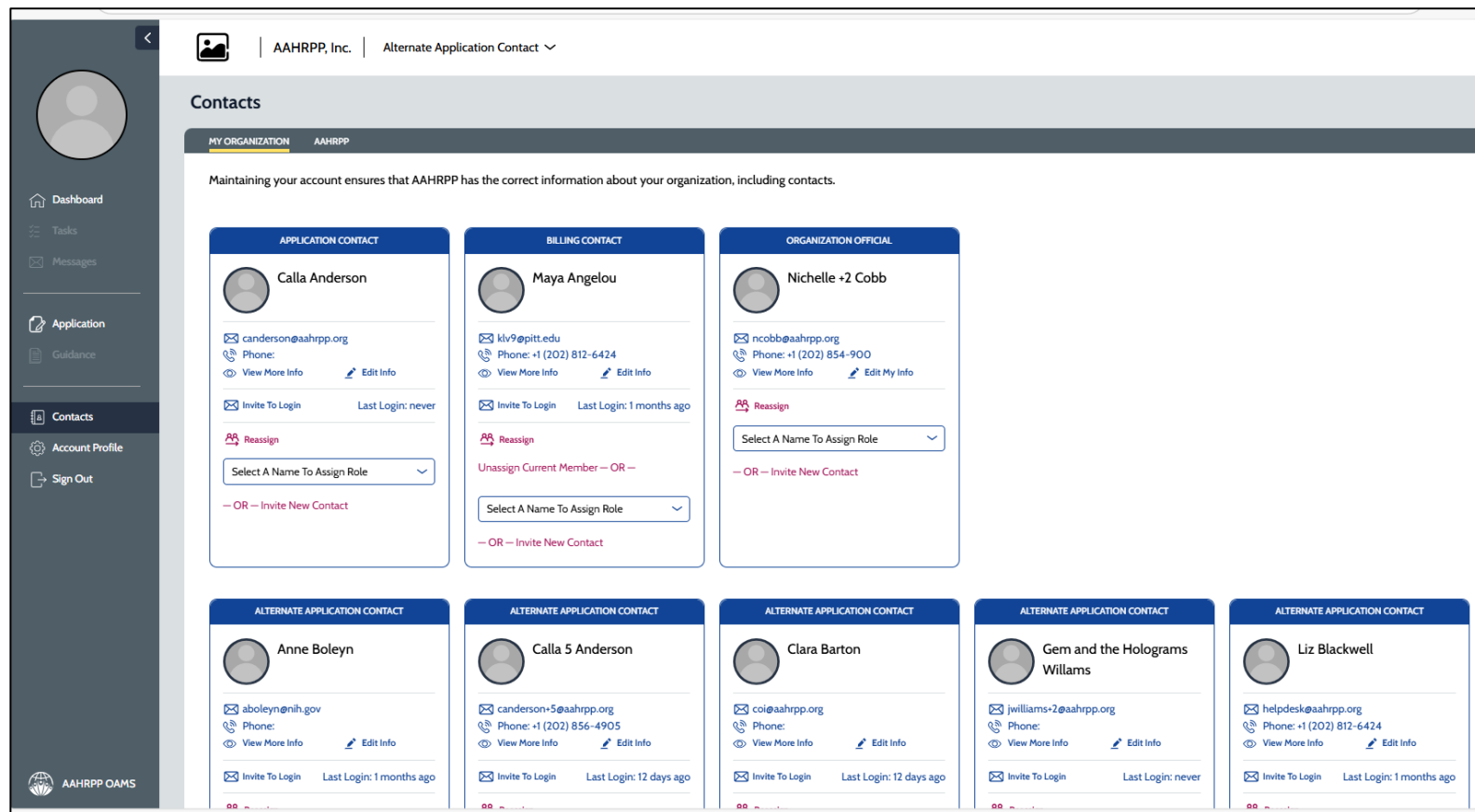
Online Accreditation Management System (OAMS)

AAHRPP is in the process of developing the OAMS to streamline applications for accreditation and required reporting to AAHRPP and already has rolled out some functionality.



Maintaining Organization Information

Once accredited, organizations are expected to maintain their organization's information in the OAMS, including the organization's contact people, such as Application Contact and Organizational Official...



AAHRPP

Alternate Application Contact

Account Profile

MY PROFILE

MY EMAILS

MY PASSWORD

ORGANIZATION

* Indicates a required field.

Organization General Information

Legal name of the organization applying for accreditation*

AAHRPP, Inc.

Name for the organization that should appear on the AAHRPP website, AAHRPP accreditation certificates, reports, and other communications from AAHRPP if different from the legal name.

AAHRPP

Organization Website

www.aahrpp.org

Organization Type

Private Entity

Organization ID#

1234

Organization Address

Street Address 1*

5335 Wisconsin Avenue NW

Street Address 2

Suite 510

Street Address 3

AAHRPP Headquarters

Dashboard

Tasks

Messages

Application

Guidance

Contacts

Account Profile

Sign Out

AAHRPP OAMS

Maintaining Organization Information

...and information about their organization, such as its legal name, preferred name, and address

AAHRPP assumes the information in the OAMS is current and accurate for organizations, so please keep it up to date.

Information about the OAMS and logging in

<https://www.aahrpp.org/resources/for-accreditation/additional-resource/online-accreditation-management-system>



Association for the Accreditation
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ONLINE ACCREDITATION MANAGEMENT SYSTEM

Latest Update: May 11, 2025



GET ACCREDITED

AAHRPP is delighted to start the rollout of the Online Accreditation Management System (OAMS) by offering accredited organizations the ability to manage information about their organizations and the profiles of Application Contacts, Alternate Application Contacts, Organizational Officials, and Billing Contacts.

Who can log into the OAMS?

- Application Contacts from all currently AAHRPP-accredited organizations.
- Alternate Application Contacts, Organizational Officials and Billing Contacts once they are invited to log in by their Application Contact.

What functionality does the OAMS currently feature?

- Organizations will manage information about their organizations as well as Application Contacts, Alternate Application Contacts, Organizational Officials, and Billing Contacts through the OAMS instead of submitting this information via Annual Reports or other forms AAHRPP previously provided (e.g., the Reportable Event Form).
- Application contacts can add an Alternate Application contact and invite them, as well as their Organizational Officials and Billing

2026 Ask AAHRPP



Save the date for 2026 "Ask AAHRPP" webinars:

- **January 13:** Conducting a Self-Assessment and building an Application
- **April 14:** Evaluation of Written Materials
- **June 9:** Evaluation of Practice – what to expect for site visit
- **August 11:** Responding to the Draft Site Visit Report
- **October 13:** Understanding the Council on Accreditation Review
- **December 8:** Responding to Council Review and maintaining accreditation

Visit [Webinars \(aahrpp.org\)](https://aahrpp.org) for more information and registration links

2026 HRPP Innovations



Dates:

February 17 : “Why HRPPs Matter”

July 14: TBD

November 10: TBD

Visit [Webinars \(aahrpp.org\)](https://aahrpp.org) for more information and registration links



2026 AAHRPP ANNUAL CONFERENCE:

GREAT LAKES, GREAT MINDS MEET IN MICHIGAN

SAVE THE DATE!

MAY 19-21, 2026

**📍 DETROIT MARRIOTT
AT THE RENAISSANCE CENTER**

**400 RENAISSANCE DR W
DETROIT, MICHIGAN**

**MARK YOUR CALENDARS FOR ONE OF THE RESEARCH
COMMUNITY'S MUST-ATTEND ANNUAL EVENTS.
MORE DETAILS TO FOLLOW.**

Contact AAHRPP

Questions About the AAHRPP Standards/Elements:

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Questions About the Application Process/Timeline:

Jemelle Williams, BS, PMP

Assistant Director of Operations

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Questions and Comments

